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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

GLENDA MCCOY and JOHN ROBERT MCCOY, for themselves as Plaintiffs, and on behalf of decedents JON ANDREA ROBERTS, MICAYLA ROBERTS, and DYLAN ROBERTS, Plaintiffs, v. PFIZER, INC., and GREENSTONE PHARMACEUTICALS, LLC Defendants.	§ § § § § § § § § § § § § § §	Civil Action No. 4:09-cv-00496

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH SUPPORTING AUTHORITIES

TO THE HONORABLE JUDGE OF SAID COURT:

Come now Plaintiffs Glenda McCoy and John Robert McCoy, for themselves as Plaintiffs, and on behalf of decedents Jon Andrea Roberts ("Andrea"), Micayla Roberts ("Micayla"), and Dylan Roberts ("Dylan") and file this Response in Opposition to Defendants' Motion for Summary Judgment with Supporting Authorities and in support thereof would show:

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I.

INTRODUCTION AND PROCEDURAL HISTORY

On July 31, 2007, Andrea and her two children, Micayla and Dylan, as well as her husband Michael, were found dead in their home, with a single gun-shot wound to the head. It appears that Decedent Andrea Roberts killed her children and husband before killing herself.[1]

Plaintiffs filed suit in the District Court for Denton County, Texas on July 31, 2009 both individually and on behalf of the estates of Andrea, Micayla, and Dylan against Defendants under the Texas Wrongful Death and Survival Acts seeking actual and punitive damages based on products liability, negligence, breach of warranty, and the Texas Deceptive Trade Practices Act.[2] Thereafter, Defendants removed this case to this Court[3] and counsel entered their appearance on behalf of Plaintiffs.[4] Defendants filed a Motion to Dismiss and Motion for Summary Judgment.[5] This Court granted in part and denied in part this motion, dismissing: (1) all claims under the Texas Deceptive Trade Practices Act; (2) all wrongful death claims except for Plaintiffs' wrongful death claim for compensatory damages based on the death of their daughter, Andrea; (3) and Plaintiffs' claim for punitive damages for the wrongful death of their daughter,[6] but denying Defendants' Motion for Summary Judgment on Plaintiffs' wrongful death claim for compensatory damages based on Andrea Roberts' death, Plaintiffs' survival claim on behalf of the estates of Micayla and Dylan Roberts, and Plaintiffs' survival claim on behalf of the estate of Andrea Roberts until the parties could conduct further discovery.[7] Additional discovery was conducted, and Defendants' filed their Renewed Motion for Partial

[1] P. Second Amended Complaint ¶12 [Dkt. 77].
[2] *Id.*
[3] Notice of Removal [Dkt. 1].
[4] Notice of Appearance [Dkt. 7].
[5] Motion to Dismiss [Dkt. 28].
[6] Report and Recommendation of United States Magistrate Judge [Dkt. 43] and Memorandum Adopting Report and Recommendation of The United States Magistrate Judge [Dkt. 44].

Summary Judgment on those same claims.[8]

On March 1, 2011, the Court entered a Report and Recommendation of Untied States Magistrate Judge.[9] The Report required that the Plaintiffs obtain consent of all heirs at law of Micayla and Dylan Roberts in order to pursue their claims.[10]

On March 31, 2011, Plaintiffs obtained and filed their Notice of Consent of Heirs at law of Micayla Roberts and Dylan Roberts.[11] Therefore, the Court denied Defendants' Motion.[12]

Accordingly, only the following claims remain: (1) the McCoys' wrongful death claim for the death of their daughter, Andrea; (2) the McCoys' survival claims on behalf of the estates of Micayla and Dylan Roberts; and (3) the McCoys' survival claim on behalf of the estate of Andrea Roberts.[13] The bases of these claims are: defective design, failure to warn, breach of warranty, and negligence.

On December 23, 2011, Defendants filed their Motion for Summary Judgment With Supporting Authorities.[14]

II.

STATEMENT OF THE ISSUE TO BE DECIDED BY THE COURT

1. Plaintiffs are not required to establish general causation through epidemiological studies; therefore, because Plaintiffs' have other general causation evidence, summary judgment should not be granted.

2. Because Defendants have directly marketed to patients, like Andrea Roberts, the learned intermediary doctrine does not apply.

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[7] *Id.*
[8] Amended Motion for Partial Summary Judgment as to Survival Claims Based on Lack of Capacity [Dkt. 54].
[9] Report and Recommendation of United States Magistrate Judge [Dkt. 64]
[10] *Id.*
[11] Notice of Consent of All Heirs at Law [Dkt. 73].
[12] [Dkt. #64 and #72].
[13] [Dkt. #43 and 44].

3. In the unlikely event the Court finds that the learned intermediary applies, Plaintiffs can establish that Defendants withheld or misrepresented required information to the FDA that was material and relevant to the performance of the product and was causally related to the claimant's injury.

III.

RESPONSE TO STATEMENT OF MATERIAL FACTS

Plaintiffs provide the following facts in dispute of those presented by Defendants:

A. ROBERTS' SUICIDE

1. On July 24, 2007, Decedent Jon Andrea Roberts ("Andrea Roberts") filled a prescription for the drug Sertraline, the generic equivalent of Zoloft ("Zoloft"), at Tom Thumb Pharmacy at 2301 Justin Road, Flower Mound, Texas 75028. Upon information and belief, Andrea had been taking samples of Zoloft in the time period preceding this prescription. During the time she was on Zoloft, Andrea Roberts became paranoid and delusional.

2. Andrea Roberts had never had any type of mental disorder or serious mental deficiency in the past. In fact, Andrea Roberts was a homemaker, mother, Girl Scout Troop leader and school Room Mother. It appears that she was prescribed Zoloft for anxiety.

3. On July 28, 2007, Andrea Roberts spoke to her mother, Plaintiff Glenda McCoy on the telephone. During this conversation, Andrea Roberts appeared to be in distress and in a manic state, to the point that her mother inquired as to whether she should travel from Missouri to Texas to be with her daughter. Andrea Roberts was clearly not herself in this conversation.

4. Andrea Roberts said she had a doctors' appointment on Tuesday, July 30, 2007, and asked her mother to wait and see what the doctor told her about how she was feeling before traveling to Texas.

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[14] [Dkt. 94].

5. In other conversations with friends, Andrea Roberts indicated that she did not feel right as a result of the medication she was taking and wanted to discuss with her doctor the possibility of being taken off the medication.

6. On July 31, 2007, Andrea and her two children, Micayla and Dylan, as well as her husband Michael, were found dead in their home, with a single gun-shot wound to the head. It appears that Decedent Andrea Roberts killed her children and husband before killing herself.

7. A note was left behind indicating that Andrea Roberts believed that her entire family had contracted the AIDs virus. The note warned anyone coming into the home to be careful about getting blood on their hands so that they did not contract AIDS as well.

8. Following the discovery of the bodies, police and officials supposedly from the Texas state government sealed all records pertaining to the case and potentially removed unknown evidence from the home and have not provided access to these materials and evidence to the surviving members of the family such that further evidence to be included in this case is unknown to Plaintiffs at the present time.

9. It is Plaintiffs' contention that the prescription drug Zoloft so affected Andrea Roberts that she was induced to commit these acts. Zoloft was the direct and primary cause of the homicides of Micayla, Dylan, and Michael Roberts and of the suicide of Andrea Roberts. As discussed below, the type of behavior exhibited by Andrea Roberts is a side effect of Zoloft that has been known to Defendants for years, but inadequately disclosed to Andrea Roberts or her treating physician.

10. Due to known side effects of the drug Zoloft, Andrea Roberts' state of mind became so impaired and her psychotic reaction became so severe, that Zoloft was the primary contributing factor to the killings and suicide.

11. Plaintiffs John and Glenda McCoy (parents to Jon Andrea Roberts and Grandparents to Micayla and Dylan) bring this action on their own behalf for the wrongful death of their daughter, Andrea Roberts, and their grandchildren, Micayla and Dylan Roberts.

12. Plaintiffs John and Glenda McCoy also bring this action on behalf of the Estate of Andrea Roberts for the torts committed by Defendants as to Andrea Roberts and for the wrongful death of Andrea Roberts' children, Micayla and Dylan Roberts, and her husband, Michael Roberts.

13. Plaintiffs John and Glenda McCoy also bring this action on behalf of the heirs of Micayla and Dylan Roberts for the torts committed by Defendants as to Micayla and Dylan Roberts and for the wrongful death of their Mother, Andrea Roberts and father Michael Roberts.

14. Defendant Pfizer, Inc. has sold the pharmaceutical drug Zoloft under the brand name Zoloft since 1991.

15. On June 30, 2006, Pfizer Inc. announced its plans to sell its own cheaper generic version of its blockbuster antidepressant Zoloft. This announcement was intended as a preemptive move to stave off competition from other generic-drug makers.

16. Pfizer, the world's biggest drug maker, announced that it would begin marketing and sell the so-called "authorized generic" through a subsidiary, Greenstone LLC.

17. Greenstone LLC is a wholly owned subsidiary of Pfizer Inc. Thus, Greenstone LLC and Pfizer have engaged in a joint enterprise under Texas law. Furthermore, Defendant Pfizer specifically created the legal entity Greenstone LLC to continue its business endeavor of selling the drug Zoloft, a drug that it developed, marketed, and for which it obtained approval by the Food and Drug Administration to sell in the United States.

B. ZOLOFT

18. Zoloft (sertraline hydrochloride) is an antidepressant. Zoloft is primarily used to treat major depression in adult outpatients as well as obsessive–compulsive, panic, and social anxiety disorders in both adults and children. In 2007, it was the most prescribed antidepressant on the U.S. retail market, with 29,652,000 prescriptions.

19. Zoloft is a member of a class of drugs known as "selective serotonin reuptake inhibitors," or "SSRI's." The first and most widely known such drug in this country is Eli Lilly's Prozac, which was approved by the FDA for marketing as an antidepressant in late 1987. Pfizer secured FDA approval to market its SRRI drug, Zoloft (under the generic name Sertraline) as an antidepressant in the fall of 1991. Pfizer introduced Zoloft onto the market later that year.

20. Pfizer touts its SSRI as a cure for a chemical imbalance in the brain, which is nothing short of speculation. As one renowned psychiatrist put it: "[SSRIs] are not correcting a biochemical imbalance, these drugs create severe imbalances in the brain." … "The idea that human suffering, psychological suffering, is biochemical is strictly a promotional campaign, perhaps the most successful in the history of the world, created by the drug companies. We do not even have a technology, a scientific technology, for measuring what happens inside the brain…it is literally a fabrication."

21. Zoloft can and does, however, cause extremely dangerous side effects including, but not limited to, emotional blunting and a condition called "akathisia," which alone or in combination with other side effects, such as emotional blunting, can cause acts of self-harm resulting in death. Akathisia is a neurological phenomenon with characteristics of intense internal restlessness, agitation and dysphoria and is known to make people suicidal. In addition, Zoloft can disrupt normal sleep patterns and structure and can also cause some patients to

become manic, hypomanic, or even psychotic, with such conditions leading to their death. In short, the drug, which appears to be no more effective than placebo, can drive some people to their death.

22. Zoloft may well help the majority of patients who take it. Unfortunately, however, there is a "small vulnerable subpopulation" of patients who are at an increased risk of violence and suicide as a result of taking Zoloft and other SSRI drugs.

23. Defendants have known about this small vulnerable subpopulation for years. And, yet, they have failed to conduct any prospective tests to determine the frequency of this phenomenon or to develop means of identifying and protecting those patients who are in this risk group. They have also failed to adequately warn prescribing physicians, pharmacists, and patients about this risk or to instruct them on the known ways to reduce or ameliorate the risk.

24. Defendants have also known for many years that Zoloft can induce akathisia, yet have failed to adequately warn either prescribing physicians or the consuming public about this dangerous condition. In fact Dr. Roger Lane, former Medical Director of the Zoloft Product Strategy Team at Pfizer, wrote two published, peer-reviewed scientific articles, which establish the causal relationship between akathisia and the risk of suicide for all SSRI drugs, including Zoloft. These articles are entitled *"SSRI-Induced extrapyramidal side effects and akathisia: implications for treatment,"* Journal of Psychopharmacology, 12(2)(1998), pp. 192-214; and *"Selective Serotonin Reuptake Inhibitor-Induced Serotonin Syndrome: Review,"* Journal of Clinical Psychopharmacology, 17(3)(1997), pp. 208-22. As Dr. Lane writes, these conditions are sometimes hard to detect and diagnose, although not so hard to treat. E.g. "SSRI-induced akathisia is a relatively rare event but is frequently unrecognized when it does occur." For this reason, is it imperative that both physicians and their patients be forewarned and alerted.

25. Pfizer has failed to adequately inform either U.S. physicians or patients of the risks documented by Dr. Lane's publications and other scientific literature. In fact, Pfizer sent a company-wide memorandum instructing the Pfizer sales force not to distribute Dr. Lane's article to prescribing physicians. Additionally, its U.S. package insert and marketing materials do not adequately warn about the risk of "SSRI-induced" akathisia, do not warn about emotional blunting, do not warn about the risk of psychosis and do not adequately warn that this drug can cause conditions that can directly lead to death.

26. Defendants aggressively distributed and marketed Zoloft, encouraging all types of physicians (including those who have no specialized training or expertise in the mental health field, like the family practitioner who prescribed Zoloft for Andrea Roberts) to dispense and prescribe Zoloft, not only for depression, but also for other maladies. As one publication, touting Pfizer, illustrates, this is consistent with Pfizer's corporate philosophy: " Research… is only half of what fuels Pfizer. The other half is marketing… At Pfizer marketing infuses every aspect of drug development and delivery…. The marketing equation is simple: If patients primed by TV commercials ask doctors, swayed by sales visits, about drugs with compelling clinical trial results, lots of prescriptions will get written." Woolley, *Science & Savvy,* Forbes, Vol. 163, No. 1, p.122,123 (January 11, 1999).

27. Until 2005, no warning at all was given regarding links between Zoloft and suicidal behavior. In fact, until that time, the only warning given about suicide at all read:

> Suicide-The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Zoloft [Sertraline] should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

28. Beginning on September 14, 2006, the following warning was included with Zoloft:

> "***Suicidality in Children and Adolescents*** Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies *in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders*. Anyone considering the use of Zoloft or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber." (emphasis added).

29. The September 14, 2006, warning was the black box warning in effect at the time of Andrea Roberts' use of Zoloft and untimely death. No mention is made in this warning about the possibility of suicide in adults. No mention is made in this warning about the potential for harm to others or to oneself. Both of these risks were known to Defendants at all times relevant to this Complaint. Defendants had a duty to warn about each of these known risks, of which it was aware.

30. On August 2, 2007, just days after the events involved in this case, this label was again changed. Beginning on August 2, 2007, the label was changed to provide:

> ***Suicidality and Antidepressant Drugs*** Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. ***Patients of all ages who are started on antidepressant therapy*** should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber." (emphasis added).

31. This new, strengthened warning, now applied to young adults as well as adolescents and, for the first time, warned that "*patients of all ages*" should be monitored appropriately and observed closely. This new warning was based on information available to Defendants well before the label change was approved by the FDA. Defendants at all times had the ability and duty to put this strengthened warning on their packaging insert for Zoloft.

32. This new warning (even if it had been given in this case) still continued to fail to advise of the risk of suicide in adult patients and failed to possibility of suicide in adults. No mention is made in this warning about the potential for harm to others. Both of these risks were known to Defendants at all times relevant to this Complaint.

33. Plaintiffs allege that the failure to provide this new, updated information to Andrea Roberts and her physician was a substantial contributing factor in the actions described in this complaint and form a basis for the tortuous allegations contained herein.

34. In addition, in Canada, prior to the events described in this Complaint, Pfizer has issued the following warning with Zoloft:

> **Adult and Pediatrics: Additional data**
> There are clinical trials and post-marketing reports with SSRIs and other newer antidepressants, in both pediatrics and adults, of severe agitation-type events coupled with self-harm or harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional liability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behavior is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioral changes.

Defendants also could have and should have issued such, or similar warning prior to the events alleged in this Complaint.

35. Plaintiffs allege that the failure to warn Andrea Roberts and her physician about the known risk of suicide and other violent behavior of certain users of SSRI drugs in general (as

described above) was a substantial contributing cause and the legal proximate cause of the actions described in this complaint and form a basis for the tortuous allegation contained herein.

36. Defendants advertise Zoloft, both in professional medical publications and, more recently, in "direct to consumer" advertising. Defendants have so aggressively marketed Zoloft, that its over-promotion has nullified even those few cryptic references to these side effects or their precursors, which do appear in the packaging contained with the Zoloft label. Thus, Defendants' legal liability is predicated, not only upon those things, which it failed to tell prescribing physicians and patients, but also on its affirmative misrepresentations.

37. On information and belief, Plaintiffs allege that Defendants, acting primarily through their bonus-incentivized sales force, went to great lengths to reassure doctors that the side effects that can lead to death which they had heard about with Prozac would not occur with Zoloft, and to assuage patients' concerns over the initial adverse effects which are frequently the harbingers of tragedy.

IV.

SUMMARY JUDGMENT EVIDENCE

Plaintiffs respectfully request that this Honorable Court take judicial notice of all pleadings on file in this case.

Plaintiffs further respectfully request that this Honorable Court take judicial notice of all Zoloft television commercials and print advertisements widely available through internet web sources such as www.youtube.com, specifically:

http://www.youtube.com/watch?v=6vfSFXKlnO0;
http://www.youtube.com/watch?v=QIFnHfdgXaA&feature=endscreen&NR=1;
http://www.youtube.com/watch?v=c2BIFSTC_vg&feature=related

Plaintiffs also include the following summary-judgment evidence in an appendix filed with this Response and incorporate the evidence into this Response by reference.

Exhibit 1: Excerpts from the deposition testimony of Brian Glaser, M.D. attached hereto as Exhibit 1 and incorporated by reference herein.

Exhibit 2: True and Correct copy of the Expert Report prepared by Glass pertaining to Andrea Roberts, Micayla Roberts, and Dylan Roberts.

Exhibit 3: True and Correct copy of the 2007 FDA-approved Zoloft (Sertraline) label as produced and provided as an exhibit during the deposition of Brian Glaser, M.D.

Exhibit 4: Excerpts from the deposition testimony of George Glass, M.D., including Exhibit 1 to his deposition containing articles referenced in Dr. Glass' Expert Report attached hereto as Exhibit 4 and incorporated by reference herein.

V.

ARGUMENT AND AUTHORITIES

A. SUMMARY JUDGMENT STANDARD

Although summary judgment is proper in a case in which there is no genuine issue of material fact, this is not a case in which the court should grant summary judgment.[15]

A defendant moving for summary judgment on a plaintiff's claim must demonstrate the absence of a genuine issue of material fact by either (1) submitting summary-judgment evidence that negates the existence of a material element of plaintiff's claim or (2) showing there is no evidence to support an essential element of plaintiff's claim.[16] A "genuine" issue is one that can be determined only by a trier of fact because it may be resolved in favor of either party.[17] A genuine issue exists when a reasonable jury could resolve the disputed fact in favor of, or in the matter described by, the nonmovant.[18] Defendant cannot rely on conclusory statements to establish that plaintiff has not presented evidence on an essential element of its claim. Rather,

[15] *See* Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).
[16] *J. Geils Band Employee Benefit Plan v. Smith Barney Shearson, Inc.*, 76 F.3d 1245, 1251 (1st Cir. 1996); *see Celotex Corp.*, 477 U.S. at 322-23.
[17] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-249 (1986).
[18] *Meadowbriar Home for Children, Inc. v. Gunn*, 81 F.3d 521, 533 (5th Cir.1996).

defendant must demonstrate the absence of a genuine factual dispute.[19]

A "material" fact is one that can affect the outcome of the suit under the governing substantive law.[20] In determining whether there is a disputed issue of material fact that prevents summary judgment, the court must consider all evidence in the light most favorable to plaintiff as the nonmovant.[21] The court must also resolve all reasonable doubts about the facts in favor of plaintiff as the nonmovant.[22] Only if defendant meets its burden is plaintiff required to respond by summary-judgment proof to show a genuine issue of material fact.[23]

Finally, in resolving a motion for summary judgment, a court may not evaluate credibility of witnesses, resolve factual disputes, or weigh the evidence.[24] "Credibility determinations are not part of the summary judgment analysis."[25] "Credibility determinations, of course, are within the province of the fact-finder."[26] "[W]hen questions about the credibility of a key witness loom [] large [], summary judgment is inappropriate."[27]

In addition, if the evidence in the record establishes that a reasonable jury, resolving all inferences in favor of the non-movant, could return a verdict in that party's favor, the motion must be denied. In *Anderson*, the Supreme Court more importantly noted that "[c]redibility determinations, the weighing of the evidence and the drawing of legitimate inferences from the facts are jury functions, *not those of the judge*, whether he is ruling on a motion for summary judgment, or for a directed verdict."[28]

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[19] *Celotex Corp.*, 477 U.S. at 324-25.
[20] *Anderson*, 477 U.S. at 248.
[21] *Garcia v. Pueblo Country Club*, 299 F.3d 1233, 1236-37 (10th Cir. 2002).
[22] *Cooper Tire & Rubber Co. v. Farese*, 423 F.3d 446, 455-56 (5th Cir. 2005).
[23] Fed. R. Civ. P. 56(e)(2).
[24] *Anderson*, 477 U.S. at 255.
[25] *Quorum Health Resources, supra*, 308 F.3d at 458 (citing *Liberty Lobby, supra*, 477 U.S. at 247-49).
[26] *Int'l. Shortstop, supra*, 939 F.2d at 1265.
[27] *Thomas v. Great Atlantic & Pac. Tea Co., Inc.*, 233 F.3d 326, 331 (5th Cir. 2000).

B. UNDER *HAVNER/GARZA* PLAINTIFFS ARE NOT REQUIRED TO ESTABLISH GENERAL CAUSATION THROUGH EPIDEMIOLOGICAL STUDIES.

Defendants misconstrue the holding in *Havner* and *Garza, i.e.* "a plaintiff ***must*** present at least two reliable epidemiological studies finding a statistically significant doubling of the risk of the outcome at issue to establish a material issue of general causation for trial."[29] *Havner* does not necessarily require epidemiological studies in order for Plaintiffs to establish general causation. Rather, *Havner* requires that general causation be evaluated based on all the evidence. "General causation" is defined by *Havner* as "whether a ***substance*** is capable of causing a particular injury or condition in the general population."[30] "Specific causation," on the other hand, concerns "whether a substance caused a particular Individual's injury."[31]

In conducting a *Havner* analysis, the court's role is not to act as a fact finder, but is instead to act as a gatekeeper determining the reliability of the expert's opinions. In determining reliability, the trial court is not to determine the truth or falsity of the expert's opinion. Rather, the trial court's role is to determine whether the expert's opinion is relevant and whether the methods and research underlying the opinion are reliable.[32] Thus, in a situation where parties are presenting competing expert opinions, based on different views of published scientific studies, the court's role is not to determine which of the two competing expert opinions it believes to be the most persuasive - that is the province of the jury.

In fact, the standards articulated in *Havner* were established because the plaintiff attempted to assert expert opinions that were contrary to the findings of approximately 30

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[28] *Anderson*, 477 U.S. at 255. (emphasis added).
[29] [Dkt. 94].
[30] *Havner*, 953 S.W.2d at 714 (emphasis added).
[31] *Id.*
[32] *Austin v. Kerr-McGee Refining Corp.*, 25 S.W.3d 280, 288 (Tex. App. . Texarkana 2000, no pet.).

epidemiological studies.[33] In order to be admissible and constitute some evidence sufficient to create a fact issue, these contrary expert opinions were required to be reliable.[34] Had the *Havner* plaintiffs presented evidence that the proffered opinions were reliable, the plaintiffs' expert opinions would have been admitted to the jury as evidence, despite the existence of the competing opinions.

Defendants assert that Plaintiffs cannot meet their burden of showing the reliability of expert opinions regarding causal relationships between Zoloft (Sertraline) and an increased risk of suicide unless that particular product has been isolated in epidemiological studies. Specifically, Defendants argue that if there is no specific epidemiological evidence satisfying various criteria discussed by The Texas Supreme Court in its analysis of the scientific proof in *Havner* (multiple published studies, peer-review, relative risk of 2.0 or greater, 95% confidence level, etc.), the Plaintiffs' expert opinions regarding a relationship between suicide and Zoloft (Sertraline) are not reliable.

Havner simply holds, pursuant to Texas Rule of Evidence 702 and *E.I. du Pont de Nemours & Co. v. Robinson*,[35] that Texas courts have a gatekeeper responsibility to make an independent evaluation of whether expert testimony is scientifically reliable and based upon sound scientific methodology.[36] In the particular case before the Court in *Havner*, the expert witnesses happened to have relied to a considerable extent on epidemiological studies for proof of general causation.[37] As a result, the Court examined and discussed the particular scientific issues involved in the evaluation of epidemiological studies at great length.[38]

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[33] *Texas Workers Comp. Ins. Fund v. Lopez*, 21 S.W.3d 358, 365 (Tex. App.—San Antonio 2000, pet. denied).
[34] *Havner*, 953 S.W.2d at 718.
[35] 923 S.W.2d 549 (Tex. 1995).
[36] *Havner*, 953 S.W.2d at 711-12.
[37] *Id.* at 715.
[38] *Id.* ("Accordingly, we consider the use of epidemiological studies and the 'more likely than not' burden of proof.").

Again, the *Havner* Court neither held nor implied that its discussion of various epidemiological concepts constituted a list of minimum requirements for the admission of evidence in all cases or in all toxic tort litigation. Indeed, the Court expressly refused to decide the type of question the Defendants seek to frame here:

> We need not decide in this case whether epidemiological evidence with a relative risk less than 2.0, coupled with other credible and reliable evidence, may be legally sufficient to support causation. ***We emphasize, however, that evidence from whatever source must be scientifically reliable.***[39]

Not surprisingly, the Court ruled that all of the supporting evidence for the proffered opinion must be considered:

> In sum, we emphasize that courts must make a determination of reliability ***from all the evidence***. Courts should allow a party, plaintiff or defendant, to present the best available evidence, assuming it passes muster under *Robinson*, and only then should a court determine ***from a totality of the evidence, considering all factors affecting the reliability of particular studies***, whether there is legally sufficient evidence to support a judgment.[40]

Therefore, because Plaintiffs are not required to establish evidence of general causation through use of epidemiological studies, Defendants' Motion for Summary Judgment should be denied.

Additionally, Plaintiffs can establish other evidence of general causation. For example the package insert issued by Defendants and approved by the FDA acknowledges that akathisia and akathisia-induced emergent suicide is a risk associated with taking the SSRI Zoloft (Sertraline). The package insert itself described findings from Defendants' clinical trials prior to FDA approval that found that adult and pediatric patients may rarely suffer from akathisia as a result of Zoloft (Sertraline).[41] Plaintiffs' and Defendants' experts agree that if a risk associated with a drug's treatment is included on the package insert, that risk is "reasonably associated"

[39] *Id.* at 719 (emphasis added).
[40] *Id.* at 720 (emphasis added).

with the treatment. Plaintiffs' expert George Glass, M.D. testified that there is a long history of studies documenting suicidality as a possible side-effect.[42] Further, that the FDA has also agreed that it is a concern; therefore, requiring it to be mentioned in black box warnings.[43] Next, Andrea's prescribing physician Dr. Glaser repeatedly testified that he *knew* of the risks of Zoloft (Sertraline) treatment—specifically, the risk of increased suicidality, and seemed to imply that he was aware that akathisia was another possible side-effect.[44] Zoloft can and does, however, cause extremely dangerous side effects including, but not limited to, emotional blunting and a condition called "akathisia," which alone or in combination with other side effects, such as emotional blunting, can cause acts of self-harm resulting in death. Akathisia is a neurological phenomenon with characteristics of intense internal restlessness, agitation and dysphoria and is known to make people suicidal. In addition, Zoloft can disrupt normal sleep patterns and structure and can also cause some patients to become manic, hypomanic, or even psychotic, with such conditions leading to their death. In short, the drug, which appears to be no more effective than placebo, can drive some people to their death.

Moreover, the inadequate and misleading label was the cause of the deaths of Andrea, Micayla, and Dylan. Defendants have also known for many years that Zoloft can induce akathisia, yet have failed to adequately warn either prescribing physicians or the consuming public about this dangerous condition. In fact Dr. Roger Lane, former Medical Director of the Zoloft Product Strategy Team at Pfizer, wrote two published, peer-reviewed scientific articles, which establish the causal relationship between akathisia and the risk of suicide for all SSRI drugs, including Zoloft. These articles are entitled *"SSRI-Induced extrapyramidal side effects*

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[41] *See* Ex. 3. 2007 FDA approved Zoloft (Sertraline) label.
[42] Ex. 4 Dep. of Dr. Glass 120/12-17.
[43] *Id.* at 120/18-22.
[44] Ex. 1 Dep. of Dr. Glaser 38/10-19.

and akathisia: implications for treatment," Journal of Psychopharmacology, 12(2)(1998), pp. 192-214; and *"Selective Serotonin Reuptake Inhibitor-Induced Serotonin Syndrome: Review,"* Journal of Clinical Psychopharmacology, 17(3)(1997), pp. 208-22. As Dr. Lane writes, these conditions are sometimes hard to detect and diagnose, although not so hard to treat. E.g. "SSRI-induced akathisia is a relatively rare event but is frequently unrecognized when it does occur." For this reason, is it imperative that both physicians and their patients be forewarned and alerted. Pfizer has failed to adequately inform either U.S. physicians or patients of the risks documented by Dr. Lane's publications and other scientific literature. In fact, Pfizer sent a company-wide memorandum instructing the Pfizer sales force not to distribute Dr. Lane's article to prescribing physicians. Additionally, its U.S. package insert and marketing materials do not adequately warn about the risk of "SSRI-induced" akathisia, do not warn about emotional blunting, do not warn about the risk of psychosis and do not adequately warn that this drug can cause conditions that can directly lead to death. For the above reasons and further discussion below, adequate warnings would have prevented this tragic event from taking place by putting not only Andrea's prescribing physician, but also her family on notice of the risk of akathisia and deadly side-effects.

C. THE LEARNED INTERMEDIARY DOCTRINE DOES NOT DEFEAT PLAINTIFFS' INADEQUATE WARNING CLAIMS

"Under Texas law, a manufacturer must instruct consumers as to the safe use of its product and warn consumers of dangers of which it has actual or constructive knowledge at the time the product is sold."[45] But where a plaintiff sues the manufacturer of a prescription drug for failing to adequately warn of the drug's effects, Texas courts employ the learned-intermediary

[45] *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir.2010) (citing *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir.1984)).

doctrine.[46] "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers."[47] Under the doctrine, a patient-purchaser's doctor acts as a conduit between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use.[48]. "If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided."[49] Accordingly, the doctrine excuses a drug manufacturer "from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers."[50] Conversely, "when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user."[51]

Although adequacy as to a warning is generally a question for the fact finder,[52] in cases involving prescription drugs involving the learned intermediary doctrine, when a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.[53] However, when a warning is either inadequate or misleading, the manufacturer remains liable for injuries sustained by the patient.[54] To recover for a failure to warn under this doctrine, Plaintiff must show (1) a defective (or misleading) warning; and (2) the failure to warn was a

[46] *Id.*
[47] *Ackermann v. Wyeth Pharmaceuticals,* 526 F.3d 203, 207 (5th Cir.2008) (citing *Alm v. Aluminum Co. of Am.,* 717 S.W.2d 588, 591–92 (Tex.1986)).
[48] *Id*
[49] *Id.*
[50] *Id.* (citing *Porterfield v. Ethicon, Inc.,* 183 F.3d 464, 467–68 (5th Cir.1999)).
[51] *Id.*
[52] *Williams v. Upjohn Co.,* 153 F.R.D. 110, 114 (S.D.Tex.1994)
[53] *Rolen v. Burroughs Wellcome Co.,* 856 S.W.2d 607, 609 (Tex.App.-Waco 1993); *McNeil v. Wyeth,* 462 F.3d 364 (5th Cir.2006).
[54] *McNeil, supra* note 3, at 368.

producing cause of his death.[55]

1. BECAUSE DEFENDANTS DIRECTLY ADVERTISED TO PATIENTS, LIKE ANDREA ROBERTS, IN A MISLEADING FASHION THE LEARNED INTERMEDIARY DOES NOT APPLY.

When a "manufacturer's direct contact with the consumer could be received and relied on by that consumer outside the learned intermediary context," the learned intermediary defense should not apply.[56] Accordingly, the learned intermediary defense should not apply in the manner suggested by Defendants in this case.

In a recent opinion, a Texas state appellate court recognized an exception to the learned intermediary doctrine in cases where a drug manufacturer practices "consumer marketing that fraudulently touts the drug's efficacy while failing to warn of the risks."[57] The court reasoned that "[t]he changes in the delivery of healthcare brought about by direct marketing and managed care demonstrate that the theoretical underpinnings of the 'learned intermediary' doctrine do not apply when a drug manufacturer directly markets to its consumers, the patients."[58] First, the court determined that "although a doctor must still write a prescription for prescription drugs, it is clear that many doctors are not spending the amount of time necessary to pass along warnings by pharmaceutical companies."[59] Second, the court opined, "by directly marketing to consumers and providing warnings in those advertisements, drug manufacturers have completely undermined their own arguments" that consumers cannot understand the warnings and that the companies "lack effective means to communicate directly with consumers."[60] Third, "consumer-directed advertising encroaches on [the physician-patient] relationship by

[55] *Porterfield*, 183 F.3d at 468. (citation omitted).
[56] *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 93 n.5. (Tex. App.—Texarkana 2000, no pet.).
[57] *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 499 (Tex. App.—Corpus Christi 2010, pet. granted).
[58] *Id.* at 507–08.
[59] *Id.* at 509.
[60] *Id.*

encouraging consumers to ask for advertised products by name."[61] The court therefore concluded that "when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its product."[62]

Since the Texas Supreme Court has not directly addressed this circumstance in the learned intermediary context. Plaintiffs' case requires this Court to determine unsettled issues of state law. "'When confronted with an unsettled issue of state law, a federal court sitting in diversity must make its best effort to predict how the state courts would decide the issue.'"[63] "'While decisions of intermediate state appellate courts provide guidance, they are not controlling.'"[64] "If a state's highest court has not ruled on the issue in question, a federal court must determine, to the best of its ability, what the highest court of the state would decide."[65] "In making an *Erie*-guess, the court can consider, among other sources, 'treatises, law review commentaries, decisions from other jurisdictions whose doctrinal approach is substantially the same, and the majority rule.'"[66] When faced with similar issues raised in *Centocor, Inc.*, the United States District Court for the Southern District in *Murthy v. Abbott Laboratories* believes that the Texas Supreme Court will likely agree with the Court of Appeals' reasoning in *Centocor, Inc.*[67]

Like the defendants in the *Murthy* case, Defendants aggressively distributed and marketed Zoloft, encouraging all types of physicians (including those who have no specialized training or expertise in the mental health field, like the family practitioner who prescribed Zoloft

[61] *Id.* (internal quotations omitted).
[62] *Id.* (*Centocor, Inc.* has been appealed to the Texas Supreme Court).
[63] *Haralson v. State Farm Mut. Auto. Ins. Co.*, 564 F.Supp.2d 616, 621 (N.D.Tex.2008) (quoting *Batts v. Tow–Motor Forklift Co.*, 666 F.3d 743, 750 (5th Cir.1995)).
[64] *Id.* (quoting *United Teacher Associates Ins. Co. v. Union Labor Life Ins. Co.*, 414 F.3d 558, 565 (5th Cir.2005)).
[65] *United Teacher Associates Ins. Co.*, 414 F.3d at 565.
[66] *Haralson*, 564 F.2d at 621 (quoting *Jackson v. Johns–Manville Sales Corp.*, 781 F.2d 394, 398 (5th Cir.1986), *cert denied*, 478 U.S. 1022, 106 S.Ct. 3339, 92 L.Ed.2d 743 (1986)).
[67] --F.Supp.2d--, 2011 WL 5416333, 8 (S.D.Tex. 2011).

for Andrea Roberts) to dispense and prescribe Zoloft, not only for depression, but also for other maladies. As one publication, touting Pfizer, illustrates, this is consistent with Pfizer's corporate philosophy: "Research… is only half of what fuels Pfizer. The other half is marketing… At Pfizer marketing infuses every aspect of drug development and delivery…. The marketing equation is simple: If patients primed by TV commercials ask doctors, swayed by sales visits, about drugs with compelling clinical trial results, lots of prescriptions will get written."[68]

These commercials and marketing advertisements paint Zoloft (Sertraline) as a "happy pill." The commercials and advertisements star a round blob that finds happiness in the form of chasing birds, butterflies, and bouncing with friends presumably from the effects of Zoloft (Sertraline).[69] Zoloft claims to correct the imbalance of chemicals between nerve receptors, which in turn corrects the complained of symptoms of depressions and social anxiety disorder. The only side effects recited during the commercials include "dry mouth, insomnia, sexual side effects, diarrhea, nausea, and sleepiness."[70] There is absolutely no mention of the possibility of akithesia or increased risk of suicide. Additionally, there is no warning that a patient should be closely monitored by caregivers and family. In other words, "fraudulently tout[ing] the drug's efficacy" or "fraudulently misrepresent[ing] the risks associated with its product."[71]

By creating and disseminating mass media and print advertisements Defendants circumvented the doctor-patient relationship and should not be released from its duty to warn Plaintiffs' Decedents of its potentially dangerous side effects. For these reasons, the learned intermediary doctrine does not apply; therefore, this Court should deny Defendants' Motion for

[68] Woolley, *Science & Savvy*, Forbes, Vol. 163, No. 1, p.122,123 (January 11, 1999).
[69] Copies of Defendants' television commercials are copyrighted, but are available on www.youtube.com at the following web addresses: http://www.youtube.com/watch?v=6vfSFXKlnO0; http://www.youtube.com/watch?v=QIFnHfdgXaA&feature=endscreen&NR=1; http://www.youtube.com/watch?v=c2BIFSTC_vg&feature=related.
[70] *Id.*
[71] *Centocor, Inc.*, 310 S.W. at 499, 509.

Summary Judgment.

2. PLAINTIFFS CAN ESTABLISH A REBUTTABLE PRESUMPTION THAT DEFENDANTS' LABEL IS INADEQUATE

Section 82.007(a) of the Texas Civil Practice and Remedies Code provides for a rebuttable presumption in certain products liability cases:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if ... the warnings or information that accompanied the product in its distribution were those approved by the [FDA] for a product approved under the Federal Food, Drug, and Cosmetic Act ... or Public Health Service Act ....[72]

This presumption may be rebutted by a claimant if he establishes that: 1) the manufacturer withheld information or made misrepresentations to the FDA before or after pre-market approval or licensing of the product; 2) the drug was sold by the manufacturer after the FDA has recalled the product or withdrawn approval of the product; 3) the manufacturer marketed the product for an indication not approved by the FDA and the plaintiff actually used it in that manner; 4) the defendant prescribed the product for an indication not approved by the FDA, or 5) the manufacturer violated 18 U.S.C. § 201 before or after pre-market approval, and that violation caused the warning or instruction approved by the FDA to be inadequate.[73]

This Court has held in *Ackermann v. Wyeth Pharmaceuticals* that the language of Section 82.007(a) creates nothing more than a presumption which a defendant is free to raise, and that if a plaintiff comes forward with evidence that the FDA was somehow misled, plaintiff has rebutted that presumption.[74]

[72] Tex. Civ. Prac. & Rem. Code Ann. §82.007(a)(1).
[73] *Id.* at 82.007(b).
[74] *Ackermann v. Wyeth Pharmaceuticals*, 471 F.Supp.2d 739, 749 (E.D. Tex. 2006).

Defendants have known for many years that Zoloft can induce akathisia, yet have failed to adequately warn either prescribing physicians or the consuming public about this dangerous condition.[75] In fact Dr. Roger Lane, former Medical Director of the Zoloft Product Strategy Team at Pfizer, wrote two published, peer-reviewed scientific articles, which establish the causal relationship between akathisia and the risk of suicide for all SSRI drugs, including Zoloft.[76] As Dr. Lane writes, these conditions are sometimes hard to detect and diagnose, although not so hard to treat. E.g. "SSRI-induced akathisia is a relatively rare event but is frequently unrecognized when it does occur." For this reason, is it imperative that both physicians and their patients be forewarned and alerted.

Nevertheless, Pfizer has failed to adequately inform either U.S. physicians or patients of the risks documented by Dr. Lane's publications and other scientific literature. In fact, Pfizer sent a company-wide memorandum instructing the Pfizer sales force not to distribute Dr. Lane's article to prescribing physicians. Additionally, its U.S. package insert and marketing materials do not adequately warn about the risk of "SSRI-induced" akathisia, do not warn about emotional blunting, do not warn about the risk of psychosis and do not adequately warn that this drug can cause conditions that can directly lead to death.

Until 2005, no warning at all was given regarding links between Zoloft and suicidal behavior. In fact, until that time, the only warning given about suicide at all read:

> Suicide-The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Zoloft [Sertraline] should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

[75] Plaintiffs'2nd amended complaint

[76] *"SSRI-Induced extrapyramidal side effects and akathisia: implications for treatment,"* Journal of Psychopharmacology, 12(2)(1998), pp. 192-214; and *"Selective Serotonin Reuptake Inhibitor-Induced Serotonin Syndrome: Review,"* Journal of Clinical Psychopharmacology, 17(3)(1997), pp. 208-22.

Beginning on September 14, 2006, the following warning was included with Zoloft:

> "***Suicidality in Children and Adolescents*** Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies *in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders*. Anyone considering the use of Zoloft or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber." (emphasis added).

The September 14, 2006, warning was the black box warning in effect at the time of Andrea Roberts' use of Zoloft and untimely death. No mention is made in this warning about the possibility of suicide in adults. No mention is made in this warning about the potential for harm to others or to oneself. Both of these risks were known to Defendants and Defendants had a duty to warn about each of these known risks.

On August 2, 2007, just days after the events involved in this case, this label was again changed. Beginning on August 2, 2007, the label was changed to provide:

> ***Suicidality and Antidepressant Drugs*** Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. ***Patients of all ages who are started on antidepressant therapy*** should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber." (emphasis added).

This new, strengthened warning, now applied to young adults as well as adolescents and, for the first time, warned that "*patients of all ages*" should be monitored appropriately and observed closely. This new warning was based on information available to Defendants well

before the label change was approved by the FDA. Defendants at all times had the ability and duty to put this strengthened warning on their packaging insert for Zoloft.

This new warning (even if it had been given in this case) continued to fail to advise of the risk of akathisia-emergent suicide risk in adult patients and failed to warn of the possibility of suicide in adults. Additionally, no mention is made in this warning about the potential for harm to others like Michael Roberts, Micayla Roberts, or Dylan Roberts.

In addition, in Canada, prior to the events at issue in this case, Pfizer has issued the following warning with Zoloft:

> **Adult and Pediatrics: Additional data**
> There are clinical trials and post-marketing reports with SSRIs and other newer antidepressants, in both pediatrics and adults, of severe agitation-type events coupled with **self-harm or harm to others**. The agitation-type events include: akathisia, agitation, disinhibition, emotional liability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment. Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behavior is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioral changes.

Defendants also could have and should have issued such, or similar warning prior to the events alleged in this case, and a warning to Michael, Micayla, and Dylan would presumably have been heeded.

For these reasons, the Court should dismiss Defendants' reliance on Section 82.007(a) as Plaintiffs have established a rebuttal to its presumption. In the alternative, Plaintiffs respectfully request this Court to decline, as it did in *Ackermann*, to recommend summary judgment based on a presumption.[77]

3. THE LABEL DID NOT ADEQUATELY INFORM DR. GLASER OF THE RISKS ASSOCIATED WITH ZOLOFT

As previously discussed, because the Zoloft (Sertraline) label had deficiencies at the time

[77] *Id. at 750.*

of Dr. Glaser's prescription to Andrea Roberts, it could not have adequately informed Dr. Glaser with respect to a patient's associated risks of akathisia and increased suicidality. Had it been an adequate warning, then there would be a presumption that Dr. Glaser would have read and heeded the warning and acted to minimize the risks.[78]

Additionally, the format of the label makes it difficult for a physician to quickly reference the risks associated with the drug and leaves no error room in diagnosis. Dr. Glaser testified that the list of side effects contained in the Physician Desk Reference (PDR) is very long and is impossible to go through with every patient.[79] In fact, despite his having testified repeatedly that he was familiar with the drug Zoloft (Sertraline) and its side effects, Dr. Glaser testified that he had never seen the list of symptoms of potential indications of emerging suicidality.[80] In addition, because the risk of akathisia induced suicide was not contained within a black box warning, and the only warning of possible akathisia, and its symptoms, was contained only in a section regarding patients with Major Depressive Disorder, Dr. Glaser did not review its warnings with Andrea Roberts.[81] In fact, the only warnings that Dr. Glaser seemed to fully understand to give Andrea, was that dealing with nausea.[82]

Following the deaths of Andrea and her family, Dr. Glaser does not prescribe Zoloft (Sertraline) with the same frequency.[83] It is not a stretch that a jury would find that had he been adequately informed and privy to all of the available findings, Dr. Glaser would not have prescribed Zoloft (Sertraline) to Andrea Roberts.

[78] *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1281 (5th Cir. 1974).
[79] *See* Ex. 1 at 35/16-24.
[80] *Id.* at 40/4-19.
[81] *Id.* at 47/2-20.
[82] *Id.* at 89/1-10.
[83] *Id.* at 58/16-24 – 59/1-7.

VI.

REQUEST FOR ORAL ARGUMENT

Plaintiffs respectfully request that this matter be set for oral argument.

VII.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs respectfully request that this Court deny the Defendants' Motion for Summary Judgment, and for such other and further relief, at law or in equity, to which Plaintiffs may be justly entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing document has been served via CM/ECF and regular U.S. mail to the following counsel this 9th day of January 2012, as follows:

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